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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/084,018 | 02/25/2002 | Olga Bandman | PF-0241-2 DIV | 8087 |
| 27904 | 7590 | 01/06/2004 | EXAMINER | |
| INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304 | | | HAYES, ROBERT CLINTON | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |
| DATE MAILED: 01/06/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/084,018

Applicant(s)

BANDMAN ET AL.

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,31,32,34,36-45 and 62-66 is/are pending in the application.
- 4a) Of the above claim(s) 44 and 45 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62-64 is/are allowed.
- 6) ☒ Claim(s) 11,31,32,34,36-43,65 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 11,31,32,34,36-45 and 62-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2/25/02.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group IIb (claims 11, 31, 32, 34, 36-43, 62, 64 and 66, as Applicants' correctly point out) with traverse in Paper No. 9/16/03 is acknowledged. The traversal is on the ground(s) that "at the very least, the restriction is improper because... there is no serious burden to examine the claims of Group IIa along with the claims of Group IIb". In that Applicants are correct that SEQ ID NO:1 is at least 98% identical to SEQ ID NO:3, in which both sequences are human variant sequences whose differences are specifically described within the specification, and which can therefore both be searched using only SEQ ID NO:3, Applicants' arguments are persuasive for rejoining Groups IIb with Group IIa. Thus, the elected invention includes antibodies directed toward SEQ ID NOs: 1 & 3 (claims 11, 31, 32, 34, 36-43 & 62-66).

Claims 11, 31, 32, 34, 36-43 & 62 (as it relates to SEQ ID NO: 5) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 9/16/03.

Allowable Subject Matter

2. Claims 62-64 are allowed, once the nonelected invention of SEQ ID NO:5 is deleted from claim 62.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 31, 32, 34, 36-43 & 65-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification on pages 3, 5 & 11 provides a written description of the human serine carboxypeptidase polypeptides of SEQ ID NOs: 1 & 3. No other "naturally occurring" serine carboxypeptidase sequences are described within the instant specification, except for the human polypeptide sequence of SEQ ID NO: 5. In contrast, the specification states that the "CPEPT... refers to the amino acid sequences of substantially purified CPEPT obtained from *any species*, particularly mammalian, including bovine, ovine, porcine, murine, equine, and preferably human". Therefore, one skilled in the art cannot reasonably visualize or predict what critical amino acid residues would structurally characterize the genus of "serine carboxypeptidase variants" claimed with various recited % identities, because it is unknown and not described what structurally constitutes these other amino acid sequences from any different species, or what sequences merely "comprise" at least 15 contiguous amino acid residues of SEQ ID NO:1 or 3 thereof that are immunogenic, which are further not described within the specification.

Applicant is directed toward the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999, and MPEP 2163.

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It is suggested that amending claims 11b, 65b & 66b to recite a "human" polypeptide, and amending claims 11d to "an immunogenic fragment consisting of [comprising] at least..." should obviate this rejection.

4. Claims 42 & 43 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the antibody is produced through "screening" a library.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
December 23, 2003

per Sig.
/600